construed by Judge Sprizzo (and a third element of the '824 patent that was never construed), and assert that those limitations are missing from the accused products. As demonstrated by Dr. Sinden and as discussed below, these elements are in fact found in each product.

1. The Accused Products are "Capable of" Indirect Detection

The Court construed the "A" limitation of claim 1 of the '824 patent and claim 42 of the '767 patent to be a signaling moiety that is "capable of indirect detection via an attached polypeptide." (Ex. 20, Claim Construction Order at 23, emphasis added). In their lead summary judgment argument, however, Defendants alternatively ignore or contort this construction by replacing the words "capable of" with "can only be." (*See* Renewed Motion at 15, "for each accused product, the fluorescent label…[is not] part of a moiety which can only be detected indirectly via an attached polypeptide.") (emphasis added).

In a holding directly applicable to this issue, the Federal Circuit found that a claim which simply requires a moiety to be "capable of performing a function" imposes "no requirement that [it] is actually present, but is infringed even in the absence of" that function -- in this case, indirect detection via an attached peptide. *Enzo*, 599 F.3d at 1342 (emphasis added); *see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d, 1358, 1370 (Fed.Cir. 2009) (holding that a component of an accused device meets the "capable of engaging" limitation even though the accused device is not designed or sold with component in engaging configuration).[15]

[15] Defendants' assertion that products with "directly detectable" labels, do not satisfy this "A" limitation literally or under the doctrine of equivalents also runs counter to the claim construction of Judge Arterton that was adopted and applied by the Federal Circuit, i.e., that the '824 and '767 patent claims cover both direct and indirect detection. *See* pp. 11-12 *supra*. To the extent Defendants argue that this Court's construction of these claims bars them from covering both direct and indirect detection, Enzo respectfully submits that clarification on this issue may be appropriate given the intervening Federal Circuit decision -- as well as subsequent admissions by key fact and expert witnesses for Defendants confirming, *inter alia*, that Example 9 of the patent discloses use of a directly detectable label. (*See* Ex. 23, Keana Tr. 85:19-87:7; Ex. 21, Blackburn Decl. ¶52; Ex. 22, Blackburn Tr. 93:9-11; Ex. 76, Ward Decl. ¶13).

That is exactly what the accused products do -- and Defendants know it. REDACTED

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REDACTED Defendants and their expert also conceded this very point in their originally-filed Joint Summary Judgment Motion:

> As both sides' experts agree, fluorescent dyes (which are themselves directly detectable) can be attached to polypeptides and used as part of an indirect detection system to detect the 'A' groups. *See, e.g.,* Blackburn Decl. ¶42-44; Ex. B (Sinden Depo.) at 101:1-102:2.

(D.I. 158, p. 15, n.22; *see also* Ex. 77, Blackburn Tr. 71:12-20 admitting that "persons of ordinary skill in the art would have understood that fluorescent molecules could be used in either direct or indirect detection methodologies.") This admission was echoed by counsel for Defendants at the summary judgment oral argument before Judge Sprizzo:

> COUNSEL FOR DEFENDANTS: We agree that fluorescent dyes in theory could be detected in that manner.... [T]his issue of, can a fluorescent dye be capable of being detected through an antibody. We agree fluorescent dyes can be detected in that way.

(Ex. 78, Hearing Tr. 183:9-10 and 189:2-5, July 17, 2007). Moreover, the other evidence of record, including the detailed analysis of Enzo's expert, Dr. Sinden, presented through hundreds of claim charts, confirms that each and every accused product[16] identified on Gunther Decl. Ex. 23 is "capable of indirect detection via an attached polypeptide" because each dye on these products is capable of binding with a polypeptide (e.g., a labeled antibody) that can then be

detected. (*See* Sinden Decl. ¶¶ 53-55 and Ex. 12; *see also* Ex. 31, Burczak Tr. 100:2-101:15; Ex. 24, Mayer Tr. 140:9-143:3; Exs. 32 and 33, Amersham and PerkinElmer specification sheets). In fact, both Amersham and PerkinElmer sell fluorescent-labeled products that are not only "capable of" indirect detection but actually have labels that are bound to antibodies. (*Id.*).

Accordingly, based on Defendants' admissions and the detailed evidence and analysis submitted by Enzo's expert, this claim limitation is met by the accused products. At the very least, the evidence and admissions raise genuine issues of material fact that preclude summary judgment, especially when viewed in a light most favorable to Enzo.

2. The Accused Products' Fluorescent Dye Molecule is Part of a Multi-component Label

Defendants also appear to argue that the accused products do not meet the portion of the Court's claim construction calling for "A" to be "one component of a multi-component signaling moiety." (Ex. 20, Construction at 23). This argument, however, is based on unsubstantiated assertions that the fluorescent dye molecule of their labels is "not part of a larger moiety" and "operates alone." (Renewed Motion at 11 and 15, respectively).

The evidence of record, including Defendants' product literature and the declarations/testimony of their own witnesses, directly refutes these conclusory assertions. For instance, REDACTED

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[16] Contrary to Defendants' arguments in their Renewed Motion, Enzo has not "abandoned" its infringement claims (p. 6), including against Orchid (fn. 10, p. 7), MPI (fn. 11, p. 7), PerkinElmer (fn. 19, p. 22), and Amersham (fn. 27, p. 33).

REDACTED Similarly, Amersham's Cy Dye-labeled NTP products and FluorX products, for example, include a fluorescent "dye group" component that is covalently attached to another "amine linker" component which, in turn, covalently attaches to the "nucleotide base" upon incorporation into a DNA/RNA strand. (Gunther Decl. Ex. 24, Burczak Decl. ¶¶ 30-55). These multi-component moieties can be seen quite clearly in Figures 1 and 2 of Defendants' Burczak Declaration wherein the "amine linker" component is circled and the fluorescent dye component is shown attached to and extending towards the upper right:

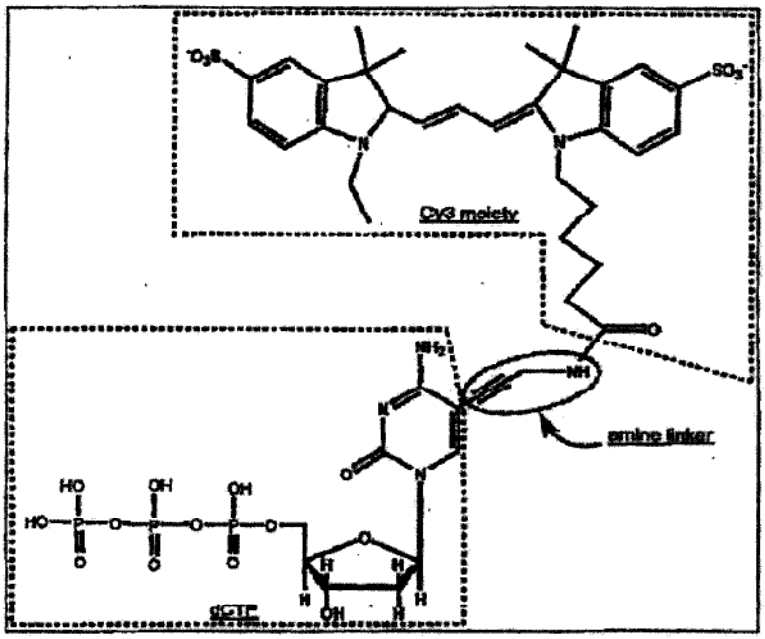


FIGURE 1

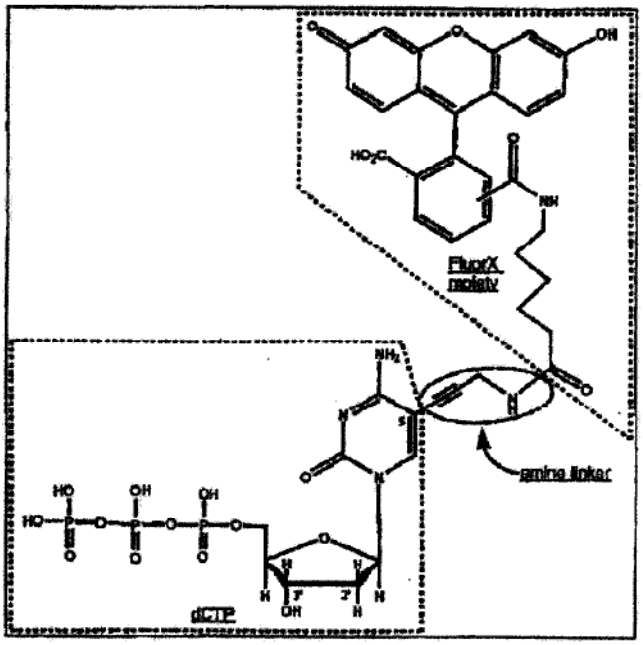
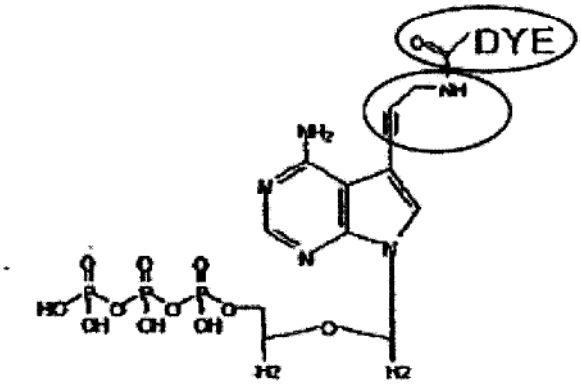


FIGURE 2

(*Id.* Figs. 1 & 2). Likewise, PerkinElmer's products, including its Acyclonucleotides and dideoxynucleotides, also include a multi-component labeling moiety that comprises a fluorescent dye component and a linker component as shown, for example, below:



(*See, e.g.*, Gunther Decl. Ex. 25; Mayer Decl. Ex. 1, at PE053621).[17] Although Enzo believes that the above evidence conclusively demonstrates that the "A" limitation is literally met, infringement under the doctrine of equivalents is also, once again, confirmed by Enzo's expert, Dr. Sinden, who relies on claim charts showing how the labeled nucleotide products of Gunther Decl. Ex. 23 infringe claim 1 of the '824 patent and claim 42 of the '767 patent upon incorporation into a polynucleotide. (Sinden Decl. ¶ 57 and Ex. 12). Indeed, the multi-component labels of the accused products perform the same ***function*** as that of the claimed limitation, i.e., to label and enable detection of a nucleic acid sequence in a way that does not substantially interfere with hybridization with its complementary nucleic acid sequence and/or detection. (Sinden Decl. ¶ 57). The ***way*** that they all perform this function is the same too, i.e., by attaching the detectable multi-component label to a specific site on the nucleic acid base.

[17] Defendants' description in their brief of what would constitute a "multi-component moiety" under the claims -- i.e., a "handle" (or "linkage group" per the patents) designed to attach to a base and another larger molecule that is detectable (without interfering with hybridization) -- literally describes the multiple components of the accused products (*see* Renewed Motion at 12-13, "The handle [i.e., linker] and the larger detectable molecul[e] [i.e., fluorescent dye molecule]…thus make up a 'multi-component' label"). (*See also* Material Fact No. 4).

(*Id.*). And so is the ***result***; in both the patents and the accused products, a detectable multi-component label is attached to a nucleic acid base at a specific location. (*Id.*).

Accordingly, based on the above evidence, including the detailed analysis of Enzo's expert, the fluorescent dyes of Defendants' products are part of a multi-component label and thus meet the "A" limitation as construed. At the very least, multiple genuine issues of fact exist which preclude summary judgment, especially when any doubts concerning these issues are resolved in Enzo's favor.

3. PerkinElmer's/Orchid's Acyclonucleotide Products Infringe

a. The Acyclonucleotides Include Nucleotides and Pentose Sugars

In its claim construction order, the Court ruled that claim 42 of the '767 patent (not the '824 patent)[18] requires "that the 'nucleotide or oligo- or polynucleotide sequence' at issue be comprised of otherwise naturally-occurring nucleotides which have been modified solely by the addition of at least one label 'A' to a nitrogenous base 'B.'" (Ex. 20 at 22-23)(emphasis added).[19]

PerkinElmer (and Orchid) argue that the acyclo products do not infringe claim 42 of the '767 patent (or claim 1 of the '824 patent) because these products allegedly lack a pentose sugar (or its equivalent) and do not include naturally occurring nucleotides. (Renewed Motion at 17-18). This argument is both factually incorrect and highly misleading. Per Defendants' own product literature, the acyclo products are incorporated into and form an integral part of an

[18] Judge Sprizzo never construed claim 1 of '824 patent to have the same scope as claim 42 of the '767 patent because Defendants never requested construction of the '824 patent. Enzo respectfully suggests that Defendants' failure to raise this construction issue during *Markman* warrants denial of their motion, particularly in view of the fact that they sought to have other constructions apply to both patents (*see* Section II.A.1, *supra*, "A" limitation construction for both '824 and '767 patents). Defendants' self-serving excuse that "the parties" did not ask for their now-asserted construction of the '824 claims because "there are no valid grounds for disputing" it, is wholly unsubstantiated, divorced from the facts and disputed.

"oligonucleotide" sequence, which includes both multiple nucleotides and pentose sugars. (*See, e.g.*, Gunther Decl. Ex. 25, Mayer Decl., Ex. 1 at PE053621, Section IV "…incorporation of a fluorescent Acyclo Terminator into a primer oligonucleotide…."; Sinden Decl. ¶ 63). REDACTED

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REDACTED Accordingly, Defendants' argument should be rejected because the acyclo products are undeniably "comprised of" (i.e., include, but not limited to)[20] both nucleotides and pentose sugars on incorporation into an oligonucleotide sequence as intended. (Sinden Decl. ¶ 63).

b. Acyclonucleotides Meet the Sugar Moiety Limitation

As Dr. Sinden explains, and as established by the claim charts attached to his declaration, the labeled acyclonucleotide products infringe claim 42 of the '767 patent (and claim 1 of the '824 patent) by meeting each and every claim limitation upon incorporation into a polynucleotide. (Sinden Decl. ¶¶ 63-66 and Ex. 11 thereto). The accused products infringe under the doctrine of equivalents because there is an insubstantial difference between the claim limitation and the accused product. (Sinden Decl. ¶ 64). The acyclonucleotide products include a "sugar" molecule (or "sugar moiety" per the '824 patent), namely, an "acyclosugar." (*Id.*).[21]

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[19] Enzo respectfully reiterates its objection to the Court's ruling that claim 42 of the '767 Patent requires the "naturally occurring nucleotides" as defined. (*Id.*).

[20] In patent parlance the term "comprising" is well understood to mean "including but not limited to." *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360-61 (Fed. Cir. 2007).

[21] Even Defendants' testifying consultant, Dr. Johannes Bauman, explained that the open-ringed structure of a similar nucleotide was a "sugar molecule which has been oxidized first." (Ex. 34, Bauman Tr. 108:2-117:14). During his deposition, Dr. Bauman was asked to write the chemical names of the individual structures on an acyclic nucleotide. (*Id.*, Tr. 107:5-114:4). Unprompted, he wrote the word "sugar" next to the acyclic sugar moiety. After a break during which he spoke to counsel for Amersham, Dr. Bauman unilaterally modified the drawing to include the word "oxidized" before the word sugar. (*Id.*, Tr. 117:10-118:14; *see also*, Ex. 35, at AM78955).

Defendants seek to distinguish these sugars based on the fact that one is cyclic or closed (pentane) and the other is acyclic or an open sugar (acyclo). From a doctrine of equivalents perspective, however, this is a distinction that makes no difference to the performance of their functions, the result or their interchangeability. (*Id.*, ¶¶ 64-65 and Ex. 18 thereto). The ***function*** of the sugar moieties in both the claim limitation and the acyclonucleotide products is to facilitate the incorporation of another nucleic base (that is labeled) into an oligonucleotide sequence so that the extended sequence can hybridize with its complementary sequence and be detected.[22] (*Id.*). The ***way*** this is done – again, both in the case of the acyclosugar and a pentose sugar – is through an enzymatic polymerase process whereby the sugar moiety of the base to be incorporated bonds with the 3' end group of the last base at the end of the sequence to be extended/labeled. (*Id.*). The ***result*** is also the same - an additional base is incorporated onto the end of the DNA chain via the respective sugar molecules and the oligonucleotide sequence is "extend[ed] by one base" (*see* Gunther Decl. Ex. 25, Mayer Decl., Ex. 1, at PE053621) (*Id.*).

A finding of equivalence, and denial of summary judgment, is also warranted by PerkinElmer's acknowledgements of the known interchangeability of the acyclonucleotide products. REDACTED

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REDACTED Additionally, the acyclo products are marked with patents that refer to their

[22] That the acyclonucleotides may also perform the additional function of chain termination is irrelevant. "[T]he relevant analysis is of the role played by each element in the context of the specific patent claim, not whether the accused element is capable of performing different roles than the claim element in other contexts." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003) (internal citation omitted). "The fact that, in other contexts, [an accused product] can perform other functions in different ways to yield a different result is not relevant." *Id.*

"acyclic" molecule as a "sugar" or "sugar portion" that persons of skill in the art knew could be used to incorporate a base into a DNA sequence. (*See* Ex. 13, '519 patent, col. 9, l. 25 - col. 10, l. 38; Sinden Decl. ¶ 66). Such evidence of the substitutability of the accused acyclo products was well known at the time of infringement and, thus, dictates a finding of infringement or, at the very least, denial of the instant motion. *See Warner-Jenkinson*, 520 U.S. at 37.

c. Defendants' Vitiation and Estoppel Theories Are Inapplicable

Defendants do not rebut *any* of the above-referenced evidence. Rather, Defendants attempt to place two legal limitations on the doctrine of equivalents, neither of which is applicable here. First, Defendants contend in conclusory fashion that a finding of equivalency would "vitiate" a sugar limitation of the patent claim.[23] As demonstrated above, however, the evidence on the function-way-result test and PerkinElmer's acknowledgements of their interchangeability would lead a reasonable jury to conclude that the "acyclosugar moiety" of the AcycloPrime products is a known equivalent substitute to the claimed "sugar moiety." *See Depuy Spine,* 269 F.2d at 1018-19. Thus, because no claim limitation has been erased, "entirely" vitiated or read "completely out" of the claim by the insubstantial differences between these substitutable sugar molecules, per the holdings cited by Defendants (Renewed Motion at pp. 8-9), the all-elements rule has not been violated. *See, e.g.*, *id.* at 1017 ("all elements" rule ensures that "no limitation be read completely out of the claim"); *Corning Glass*, 868 F.2d at 1259 (claim element not vitiated where it was not "entirely missing").

[23] Even assuming, *arguendo*, that Defendants' general vitiation theory is correct (it is not), Defendants err in seeking to apply the theory to a term in the preamble of claim 42 of the '767 patent that they have not shown to be a positive limitation of the claim. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) ("Generally, the preamble does not limit the claims.")

Defendants' second argument for limiting the doctrine of equivalents is that arguments (not amendments) made during prosecution, including a separate patent not at issue on this motion (i.e., the '955), somehow result in a "clear and unmistakable surrender" of the particular equivalents in question, namely the use of an acyclosugar in an acyclonucleotide. On this, the law is equally clear. Mere use of the word "nucleotides" at various points in the prosecution of related patents does not result in the sort of "clear and unmistakable surrender[]" of claim scope that is required. *See Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008).

Defendants point to arguments in the prosecution of the Ward patents' parent application that they acknowledge as being directed to "other types of molecules" (Renewed Motion at 18), but neglect to mention were "concerned with pyrimidine nucleosides" and not the equivalent subject matter at-issue. (*See* Ex. 37 at 3). Thus, assuming, *arguendo*, that the arguments during prosecution rose to the level of the required "clear and unmistakable surrender" (they do not), the scope of any such estoppel would, at most, be limited to *pyrimidine nucleosides* and not the distinctly different subject matter of "non-pentose sugars" that Defendants suggest.[24] (*See id.*). Similarly, the prior art references (Brandon and Hayashi) cited by the Patent Office during

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[24] The fact is that the scope of any estoppel would necessarily be even narrower than "pyrimidine nucleosides" because that was only one of several bases for distinguishing the prior art (Ruth and Bergstrom) including the fact that they: were not capable of being incorporated in and effective in double-stranded DNA; "could not be used for labeling polynucleotides *in vitro*" (Ex. 37 at 4-5); required a different procedure for purification (*id.* at 5); and were proposed as antiviral agents whereas preparation of the claimed nucleotides would have no antiviral activity (*Id.* at 4). Thus, the scope of any potential estoppel would encompass all of these combined distinctions not each of them individually, and, thereby, be much narrower than what Defendants seek. *See Read Corp.* 970 F.2d at 824 and n.4:

> "Acceptance of Portec's argument respecting estoppel for each item in a patentee's list of distinctions between the invention and a prior art reference would mean that the less material a prior art reference, the more the estoppel merely by a patentee's pointing out numerous differences. This turns an equitable doctrine into an illogical mechanical rule and would allow easily distinguishable prior art .... to emasculate the doctrine of equivalents."

prosecution of the '955 patent application (not the '824 or '767) were not acyclonucleotides but rather were distinguished because they only refer to bases without sugars and concerned the synthesis (i.e., creation) of a nucleotide base (Ex. 38 at 26). Acyclonucleotides are not bases without sugars and no reasonable competitor would understand that the applicant had surrendered the accused sugar-containing acyclo products. *See Catalina*, 289 F.3d at 813. Indeed, neither acyclonucleotides with an acyclosugar moiety, nor sugar moieties in general, are mentioned anywhere -- let alone unmistakably disclaimed -- in the Responses to Office Actions relied on by Defendants. Accordingly, when viewed in the proper context, there was no "clear and unmistakable" surrender of the subject matter at-issue by the patentees. *See Conoco*, 460 F.3d at 1364 (argument distinguishing "fatty acid wax" from prior art metal stearates held to be a clear disavowal of metal stearates but not all fatty acid wax equivalents).

d. PerkinElmer's Admissions of Infringement of the "Dominated" Acyclo Products in its Settlement Agreement

In 1999, to induce Enzo to enter into a Distribution Agreement, PerkinElmer entered into a Settlement Agreement with Enzo to resolve the issue of NEN's past infringement of Enzo's patents. (Ex. 12). In the Agreement, PerkinElmer stipulated and agreed that PerkinElmer infringed Enzo's patents-in-suit and that Enzo's patents "dominate" U.S. Patent Nos. 5,151,507, 5,047,519 and 5,608,063 (the "DuPont Patents"), which are directed to the acyclonucleotide products. (*Id.* at ¶1-2; *see also* Ex. 16).

According to "established patent law terminology," a patent "dominates another if a claim of the first patent reads on a device built or process practiced according to the second patent disclosure." *In re Kaplan*, 789 F.2d 1574, 1577 (Fed. Cir. 1986). In other words, "the more narrowly claimed invention cannot be practiced without infringing the broader claim." *Id.*

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REDACTED PerkinElmer marked these acyclonucleotide products with two of the DuPont patents and the statement that "[t]hese alkynylamino-acyclic analogs are covered by U.S. Patents 5,047,519 and 5,151,507". (Ex. 16).[25] Thus, having admitted that Enzo's patents "dominate" the Dupont Patents – that is, that they cannot be practiced without infringing Enzo's patents – PerkinElmer should be held to these admissions which squarely undercut their present contentions that the acyclo products do not infringe Enzo's '824 and '767 patents.

At the very least, these "intensely factual" and disputed issues surrounding infringement of claim 42 of the '767 patent (and claim 1 of '824 patent) by the acyclo products, including the insubstantiality of differences, their known interchangeability, and Defendants' admissions against interest, preclude summary judgment. Disputes over "their evidentiary value" (Renewed Motion at 20) are properly for the jury to decide. *Vehicular Techs.*, 212 F.3d at 1381.

4. The Dideoxynucleotides Infringe Claim 1 of the '824 Patent

Defendants present another non-infringement argument with respect to claim 1 of the '824 patent that is based on a claim construction not found in the court's order because they never asked for or obtained it during the *Markman* process. Despite not having sought or obtained their newly-minted construction, Amersham and PerkinElmer argue that this claim requires "a phosphate group at the third position of a nucleotide[]." (Renewed Motion at 12). This unduly restricted construction and non-infringement argument should be estopped/denied as untimely and contrary to their prior admissions and the intrinsic evidence.

First and foremost, PerkinElmer marked their dideoxynucleotide products with the '824 patent (*see* Ex. 41, *e.g.*, pp. PE081146-49; Ex. 42, PerkinElmer notice to Amersham that products had to be marked with the '824 patent), and thus, for all of the factual and legal reasons

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detailed above in Section II., *supra*, PerkinElmer should be precluded from denying infringement. *Elite Licensing*, 250 F. Supp. 2d at 386; *Gridiron Steel*, 361 F.2d at 797.

PerkinElmer should also not be permitted to seek summary judgment for these "marked" products based on a proposed construction that they never raised or permitted Enzo and the court to properly address (and reject) during the *Markman* process. Besides being untimely, Amersham's and PerkinElmer's proposed claim construction is also scientifically incorrect (Sinden Decl. ¶¶ 67-69) and inconsistent with the claim language and patent. Upon review of claim 1 and the patent disclosures, persons of ordinary skill in the art would immediately recognize that this claim does not require "a phosphate group attached to the 3' position of the labeled nucleotide" as Defendants contend. (*Id.*). As explained by Dr. Sinden, the patent claim explicitly covers both the situation where a phosphate group is present as well as the situation where it is not. (*Id.*). Persons of skill would understand this from the language of claim 1 which specifically contemplates and allows for "p" to be zero. (*Id.*). In such an embodiment of the claim, there can be no phosphate group on the preceding "n" nucleotide because "n" would be the terminal nucleotide of the DNA strand. (*Id.*). In other words, persons of skill in the art reading the patent specification and claim language would understand it to cover a product where a phosphate need not be present (i.e., where $m \geq 1$, $n = 1$, and $p = 0$). (*Id.*).

Consistent with Defendants' marking and other pre-suit admissions that the dideoxynucleotide products were covered by Enzo's patents-in-suit (Ex. 12, at ¶¶ 1-3), Dr. Sinden's declaration also confirms that the products listed on Gunther Decl. Ex. 34 meet each and every limitation of claim 1 of the '824 patent. Sinden Decl. ¶¶ 62-69 and Ex. 13 thereto.) Specifically, the labeled nucleotide products depicted on the claim charts infringe claim 1 of the '824 patent upon incorporation into a polynucleotide. (*Id.*).

In view of the above, Defendants motion as to these "marked" products and their new and unsupported claim construction should be denied.

IV. Defendants' Products Infringe The '373 Patent

Enzo has asserted that Defendants Amersham, Affymetrix, PerkinElmer and Roche have infringed claims 1, 17 and 18 of the '373 patent. For a complete listing of products infringing these claims, see Exhibit 4. Relying on specification sheets for the accused products, Enzo's expert, Dr. Archibald Perkins, analyzed and found infringement on an element-by-element basis of the claims of the '373 patent, and attached detailed claim charts of this infringement analysis. (Perkins Decl. ¶¶ 14-61, Exs. 4-10).[26] Again, Defendants have not and cannot dispute this evidence. Instead, Defendants point to two elements of the '373 patent as they were construed by Judge Sprizzo, and insinuate that those limitations are not found in the accused products. As demonstrated by Dr. Perkins and as discussed below, these elements are in fact found in each product.

A. The Complementary Nucleic Acid Sequences of the Patent and Accused Products are Interchangeable and Defendants' Rearranging of Their Position is an Insubstantial Change

In the first part of the construction of claim 1 of the '373 patent, the Court found that "the sample, which is the substance within which one is looking for the presence of the analyte, must be fixed to the solid support, and that the probe, which is a labeled sequence complementary to the analyte, cannot be so fixed." (Ex. 20, Claim Construction Order, at 24). Enzo does not dispute that there is no literal infringement because in the accused products the positions of the two complementary polynucleotide sequences are switched, i.e., the probe sequence is fixed to the solid support and its complementary sequence is kept unfixed.

[26] Dr. Perkins analyzed and found infringement of Claim 1, and dependant Claims 2-3, 5-7, 10, 13, 15 and 17-19, as well as dependent claims 8-9 and 11-12 (by Affymetrix only).

The record, however, shows that it is no more than an insubstantial difference to affix one or the other of these complementary polynucleotide sequences to the solid support (including the probe sequence) while keeping the other complementary sequence unfixed and labeled in solution. At the time of infringement, a person of ordinary skill in the art would have recognized the interchangeability of these complementary polynucleotide sequences. (Perkins Decl. ¶¶ 38-44). *See Warner-Jenkinson*, 520 U.S. at 37 ("[T]he proper time for evaluating equivalency … is at the time of infringement, not at the time the patent was issued.")

Defendants' conclusory argument that such a mere rearrangement of the location of the complementary sequences would "vitiate" the requirements of '373 claim 1 is simply unfounded. The fact is, no limitation ends up "missing," excluded, or vitiated by the mere switching of location of one complementary polynucleotide sequence for the other. One of the two complementary polynucleotide sequences is affixed and the other is unfixed and labeled - their positions are simply rearranged. As the Federal Circuit has held:

> Infringement may not be found under the doctrine of equivalents if a limitation is missing, that is, not replaced with an equivalent substituent... the substituent need not be in the exact same location specified by the claim. If, in the context of the invention, the substituent substantially performs the same function to achieve the same result in the same way as the required limitation, that limitation is satisfied.

Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1568 (Fed. Cir. 1996) (emphasis added). Thus, although Defendants may dispute it, in terms of criticality to the function, way or result of the invention, this simple format rearrangement is a distinction that makes no real difference.[27]

[27] Defendants' supposed differences based on mass production capabilities and additional experiments are, at best, disputed issues of fact over proper application of the function/way/result test that are properly resolved by the jury not on summary judgment. *See Overhead Door*, 194 F.3d at 1270-71. They are also irrelevant because it does not matter that an accused product may perform additional functions or be better or more efficient. *See Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984) ("infringement cannot be avoided by the mere fact that the accused devise is more or less efficient or performs additional functions.").

Markman v. Westview Instruments, Inc. 517 U.S. 370, 373-74 (1996). (A patent claim "functions to forbid not only exact copies of an invention, but products that go to the heart of the invention but avoid the literal language of the claim by making a noncritical change.")

Indeed, as explained by Dr. Perkins, the analyte and probe polynucleotide sequences are complementary to each other. (Perkins Decl. ¶ 49).[28] In terms of both the disputed claim limitations and the accused products, the mere rearrangement of the position of one complementary polynucleotide sequence for the other does not make a difference (let alone a substantial difference) in accomplishing the ***function*** of detecting the presence and/or quantity of a polynucleotide sequence via hybridization with its complementary polynucleotide sequence. (*Id.*, ¶ 50).[29] Likewise, whether the label is attached to an unfixed analyte or probe sequence it still performs that same function in the same ***way***, i.e., by hybridizing the unlabeled polynucleotide sequence that is secured to a solid support with its unfixed free-floating complementary sequence that is labeled. (*Id.*).[30] In this way, the same ***result*** is achieved of

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[28] In footnotes 23 and 26 of their brief, Defendants attempt to discredit the expert evidence presented by Dr. Perkins rather than attack it substantively. First of all, Dr. Perkins has revised his declaration to remove any question of whether his opinions are directed to equivalency of the individual claim limitations. More importantly, the evidence shows that at the time of infringement, a person of skill in the art would have known, as the Court has recognized (Ex. 20, Claim Construction Order at 20), that the invention would not work if the sequence that is fixed to the solid support were to be labeled and, thus, that person would know to keep the label on whichever sequence is unfixed. (Perkins Decl. ¶ 46). The only difference then between the claimed and accused methods is the switch of the location of the complementary sequences because a person of skill in the art would know that the claimed label remains on whichever of the complementary sequences is not fixed to the solid support. (*Id.*).

[29] Notably, when Defendant Roche sought to patent the accused products on this basis, the U.S. Patent & Trademark Office rejected an argument of unique differences between fixing the probe instead of the analyte sequence as "semantic in nature rather than functional." (Ex. 43, Office Action in Roche U.S. Patent Applic. No. 07/414,542, dated Mar. 2, 1992, at 5).

[30] Both the Court and the parties have acknowledged (Ex. 20, Claim Construction Order at 19) that once the switch is made, the function would be carried out in the same way:

detection and/or quantitation of a polynucleotide sequence of interest. (*Id.*). Thus, simple reciprocal rearrangement of the location of these complementary polynucleotide sequences exalts form over substance and is not the "opposite"[31] of the claimed format but an insubstantial difference. *See Sanitary Refrigerator*, 280 U.S. at 41-43 ("A close copy which seeks to use the substance of the invention, and although showing some change in form and position, uses substantially the same devices, performing precisely the same offices with no change in principal, constitutes an infringement" because "one alone of these changes cannot be substituted...without the other, so as to make it operative");[32] *Corning Glass*, 868 F.2d at 1258-61 (adding "negative dopant" to *negatively* alter the refraction index in a *cladding* component was equivalent to adding "positive dopant" to *positively* alter the refraction index in the other *core* component).

> "All parties agree that it is possible for the test just described to be conducted by attaching unlabeled single-stranded probes to the solid surface and then introducing labeled strands of the sample. If the sample contains DNA or RNA complementary to the probe (that is, if the analyte is present in the sample), then hybridization will occur and *the same steps will be taken to detect the presence of the label*. *See, e.g.*, Hr'g Tr. at 308, 520-21." (emphasis added)

[31] Even situations involving true "opposites," rather than the simple rearrangement at-issue, would not preclude the doctrine of equivalents -- but would, on the other hand, preclude summary judgment if substantiality of the alleged differences is disputed. *See Dyson v. AmWay Corp.*, 1991 WL 193513, at *3 (W.D. Mich. Jan. 9, 1991) (summary judgment denied based on a dispute over whether "top" is equivalent to "bottom" including the known interchangeability of the location); *Lean Auto. Dearborn, Inc. v. Johnson Controls, Inc.*, 528 F. Supp. 2d 654, 666 (E.D. Mich. 2007) (summary judgment denied based on dispute over whether accused "decryption" was insubstantially different from claimed "encryption"); *Speedplay, Inc. v. Bebop Inc.*, 1996 WL 33649180, at *5, n.4 (S.D. Cal. Sept. 25, 1996) (summary judgment precluded by dispute over whether "hollow" pedal met "solid" pedal limitation).

[32] In *Sanitary Refrigerator*, the accused device made two changes to the patented structure: the insertion of a "lug" on the keeper and shortening of the upper arm so that it contacts the lug rather than the side of the keeper per the plaintiff's patent. *Id.* at 41. The Supreme Court held that the accused device met the function-way-result test, because these "two reciprocal changes" to the form and position of the patented structure were insubstantial. *Id.* at 42-43.

The evidence of known interchangeability of the location of these complementary polynucleotide sequences further confirms and establishes their equivalence. (Perkins Decl. ¶¶ 39-40, 49). Notably, Defendants do not challenge this evidence on the merits but ask the court to disregard it as an "improper application of the function-way-result test" (Renewed Motion at 31, n. 23). Known interchangeability, however, is an objective consideration on the question of equivalence that is separate and distinct from the above-analyzed function-way-result test. *Warner-Jenkinson*, 520 U.S. at 36. As set forth in Dr. Perkins' declaration, a person of skill in the art would not have understood the patentees of the '373 patent to have disclaimed, dedicated, or otherwise disavowed any unclaimed subject matter of equivalents of the claimed invention. (Perkins Decl. ¶ 45). The *SciMed* case relied on by Defendants is inapplicable because there are no "clear and binding" statements in the patent that the invention must be practiced only by the claimed arrangement nor that the equivalent arrangement of the accused products are excluded from use. *SciMed*, 242 F.3d at 1347. To the contrary, the record evidence shows that at the time of infringement one of skill in the art would have recognized the complementary polynucleotide sequences as interchangeable with each other. (Perkins Decl. ¶¶39-40, 49). *See Overhead Door*, 194 F.3d at 1269-70.

Likewise, Defendants' dedication to the public argument, and the *PSC Computer* and *Pfizer* cases they rely on, are also inapplicable to the instant facts. "[B]efore unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter *must* have been identified by the patentee as an *alternative* to a claim limitation." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005) (emphasis added). Example 5 in the '373 patent, which forms the basis of Defendants' allegations of what Enzo allegedly "dedicated," does not disclose the rearranged format employed by Defendants that is accused of

infringement. In fact, the part of the example involving the fixing of a probe on a solid plastic surface does not describe a hybridization reaction at all. (Perkins Decl. ¶ 45). Rather, it is an experiment to determine how much of a probe sequence will stick to a particular plastic surface (treated v. untreated). (*Id.*). Thus, this disclosure does not involve, disclose, or dedicate any of the claimed features of the use of a complementary polynucleotide sequence, hybridization of two sequences, or detection of the hybridized material -- and so cannot be considered an "alternative" embodiment of the claimed invention, let alone the accused method used by Defendants. (*Id.*).[33] *See Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 527 (S.D.N.Y. 2002) (no dedication to public where patent specification did not disclose the specific combination of features used in the accused products); *Tuna Processors, Inc. v. Haw Int'l Seafood, Inc.*, 2006 WL 2989248 at *4 (D. Haw. Oct. 17, 2006) (dedication to the public is limited to the specific subject matter disclosed in the specification). If anything, the disputed statement in Example 5 of the '373 patent that "the advantages of this invention are also obtainable when the probe is immobilized on a non-porous plastic surface" is nothing more than some objective affirmation that, at the time of infringement, persons of skill in the art reading the patent would have understood the simple switch of location as a mere design choice based on the other objective knowledge they would have had. (Perkins Decl. ¶ 46). *See Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1316 (Fed. Cir. 1999) (infringement under doctrine of equivalents affirmed where accused and claimed structures were shown by expert testimony to be known substitutes).

[33] Defendants' expert, Dr. Stark -- who they do not cite in support of the dedication of the public argument -- did not opine that this was an "alternative" embodiment but rather "concluded that Example 5's one mention of a fixed probe was a drafting mistake." (D.I. 131, Defendant's Post-*Markman* Reply Brief, citing Dr. Stark's *Markman* testimony, Ex. 79, Hearing Tr. 539:15-19.)

Accordingly, the above factual disputes over what a person of skill in the art would understand concerning these issues of proper application of the function-way-result test, known interchangeability of the analyte and probe, the reciprocal nature and criticality (or lack thereof) of such substitution, and whether the patent would be read to support or disclaim/dedicate such equivalents, all raise genuine issues of material fact that, at this stage, should be resolved in Enzo's favor and render summary judgment inappropriate.

B. Defendants' Accused Products Meet The Soluble Signal Limitation

Per the second part of the Court's *Markman* decision, the chemical label attached to the unfixed polynucleotide sequence must, after hybridization, be capable of generating a "soluble signal" or "a soluble, or uniformly dispersed, product which generates a detectable signal." (Ex. 20, Claim Construction Order, at 24). As demonstrated below, Defendants' products meet the soluble signal limitation of the claims.

As explained by Dr. Perkins with respect to this limitation, the chemical label that is capable of generating a soluble signal -- in both claim 1 of the '373 patent and the Defendants' products -- is a fluorescent "label" component that is attached to the unfixed complementary polynucleotide sequence. (Perkins Decl. ¶ 29; *see also* Ex. 44, McGall Tr. 171:20-172:5; Ex. 45, Will Tr. 61:9-62:5). Following hybridization of the complementary polynucleotide sequences this attached fluorescent label produces a detectable signal. The signal never precipitates and, thus, is not "insoluble." (*Id.*). Rather, it is a "soluble signal" in the form of light photons that are uniformly dispersed in solution and detected by a spectrophotometer. (Perkins Decl. ¶ 29). Accordingly, the accused products meet the literal language of this element as construed.[34]

[34] Dr. Perkins analyzed and concluded that there was infringement under Judge Sprizzo's construction as well as Judge Arterton's subsequent construction which defined "soluble signal" as a "signal that does not precipitate and is thus detectable by spectrophotometric. . . techniques, such as. . . fluorescent signals." (Ex. 19, 2006 WL2927550, at *13-14). Enzo respectfully

The accused products also infringe under the doctrine of equivalents. Again, per the declaration of Dr. Perkins, the ***function*** of the soluble signal limitation of the '373 patent is to enable the detection and/or quantitation of the presence of a targeted polynucleotide sequence. (*Id.* at ¶ 30). The ***way*** this is performed is through the use of at least one detectable signal such as fluorescence (light) that does not precipitate. (*Id.*). A fluorescent soluble signal emits light photons that uniformly disperse in solution. (*Id.*).[35] The ***result*** is the detection and quantitation of a polynucleotide sequence of interest. (*Id.*). Thus, the function/way/result test is met by the accused products. The fluorescent label and corresponding detectable signal of the accused products would also be understood by persons skilled in the art as interchangeable with the claimed limitation particularly in view of the clear recitations of the '373 patent claims that the soluble signal can be transmitted "light" (e.g., claim 13) that can be generated by a "fluorescent" molecule (e.g., claims 3, 15 and 19), and detected by the same "spectrophotometric techniques" (e.g., claims 13 and 2) that are employed by the accused products. (*Id.*, ¶ 31).[36]

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submits that to the extent Defendants contend in their Reply that there are any aspects of these constructions that are at-odds with each other, clarification to resolve such purported inconsistencies is appropriate and within the court's authority. *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) (permitting court to engage in "rolling claim construction"); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1253 (Fed. Cir. 2011) (encouraging "consult[ation of] the claim analysis of different district courts on the identical terms in the context of the same patent" to promote uniformity).

[35] Defendants' expert witness, Dr. Blackburn, agreed that the light emitted from a fluorescent molecule is emitted in all directions, like a light bulb, not a laser pointer which emits a focused beam of light. (Ex. 80, Markman Tr. 738:1-739:4, July 11, 2005). The explanation in their Renewed Motion (p. 24) of how a "colored" product is a "soluble signal" is also descriptive and equally applicable to the accused fluorescent product: "[photons] of the detectable product are released into the surrounding solution. . . . As more [photons] enter the solution, the [light] intensity increases. This change in intensity can then be detected."

[36] Defendants' argument that so-called "tethered" fluorescent molecules are "outside the scope of the patent claims" (Renewed Motion at 32-33) fails to address in any meaningful way Dr. Perkins' analysis under the doctrine of equivalents or explain how or why it is substantially different from the claimed chemical labels including those which explicitly call for "tethering" or covalent/direct attachment of fluorescent chemical labels capable of generating the claimed

Accordingly, the accused products meet the soluble signal limitation of the '373 patent. At the very least, the above evidence, including the declaration of Enzo's expert, Dr. Perkins, warrant denial of summary judgment of non-infringement.

V. Roche's And PerkinElmer's Distributorship Agreements With Enzo Do Not Bar Enzo's Infringement Claims Against "Unauthorized" Activities

Because the defense of "payment" under "license" or "authority" asserted by Roche and PerkinElmer turns heavily on contractual issues, Defendants have violated the Court's August 25, 2011 order limiting the scope of the instant renewed motion to "patent issues only." (*See* Docket No. 247). In any event, Roche's and PerkinElmer's defense is meritless.[37]

According to Defendants, "[t]heir only argument is … that they were expressly authorized to manufacture and sell the products covered under the distribution agreements, and having granted them that authority, Enzo has no right to sue them for patent infringement for exercising that authority." (Renewed Motion at 35). Defendants have not carried their burden of proving their defense that all of the products they made and sold actually fell within the scope of the explicitly limited scope of authority that had been granted by Enzo -- REDACTED

REDACTED

REDACTED

REDACTED Indeed, rather than trying to establish that the sales in question were authorized (i.e, to "research" entities solely for "research purposes" and not for commercial purposes), Defendants carefully avoid the actual language of the Distribution

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soluble signal. (*See*, *e.g.*, Ex. 7, claims 18, 19 and 27). This tactic may be one way to avoid a dispute over the facts, but it falls far short of carrying their heavy burden on summary judgment.

[37] Amersham does not even attempt to submit any evidence to support its bare assertion that "payment under the agreement would have been a complete defense to alleged infringement" (Renewed Motion at 33 n.27), and thus fails to satisfy its heavy burden to demonstrate the absence of any genuine dispute of material fact.

Agreements and the circumstances surrounding their accused activities. Their naked assertions that they were "authorized", however, simply do not suffice to carry their burden. Because the evidence of record shows numerous instances of activities that exceeded the explicitly limited "authority" granted to them under their respective Agreements, both of the Defendants are liable for patent infringement. At the very least, their failure to establish the nature of their accused activities and dispel the numerous disputed issues of fact precludes summary judgment.

A. Defendants Misstate the Law on License and Exhaustion

The crux of this motion -- that is nowhere addressed by Defendants -- is whether they in any way exceeded the strictly limited scope of authority granted to them under their respective Agreements.[38] If they did, then the law is clear that any such facts beyond the scope of authority is infringement. *See* 35 U.S.C. § 271(a) (establishing liability against "whoever *without authority* makes, uses, offers to sell, or sells any patented invention) (emphasis added); *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625-26 (2008) ("[T]he initial *authorized sale* of a patented item terminates all patent rights to that item") (emphasis added). Indeed, even a purported licensee's conduct that exceeds the scope of the authority granted to it constitutes patent infringement. *Gen. Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 181-82 (1938); *Symbol Techs., Inc. v. Hand Held Prods., Inc.*, No. Civ. A 03-102-SLR, 2003 WL 22750145, at *2 (D. Del. Nov. 14, 2003); *cf. Harrell v. Van der Plas*, No. 08 Civ. 8252, 2009 WL 3756327, at *2 (S.D.N.Y. Nov. 9, 2009) ("It is black-letter law that a claim for copyright infringement lies when a party's use of copyrighted material exceeds the scope of its license.")[39]

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[38] Defendants mention the words "research market" only once on page 36.

[39] Defendants' reliance on *Genetic Implant Systems* for the proposition that they have an unbounded license to make, use and sell, products covered by Enzo's patents is misplaced. That case does not construe a contract to determine the scope of a "license" (express or implied); it is

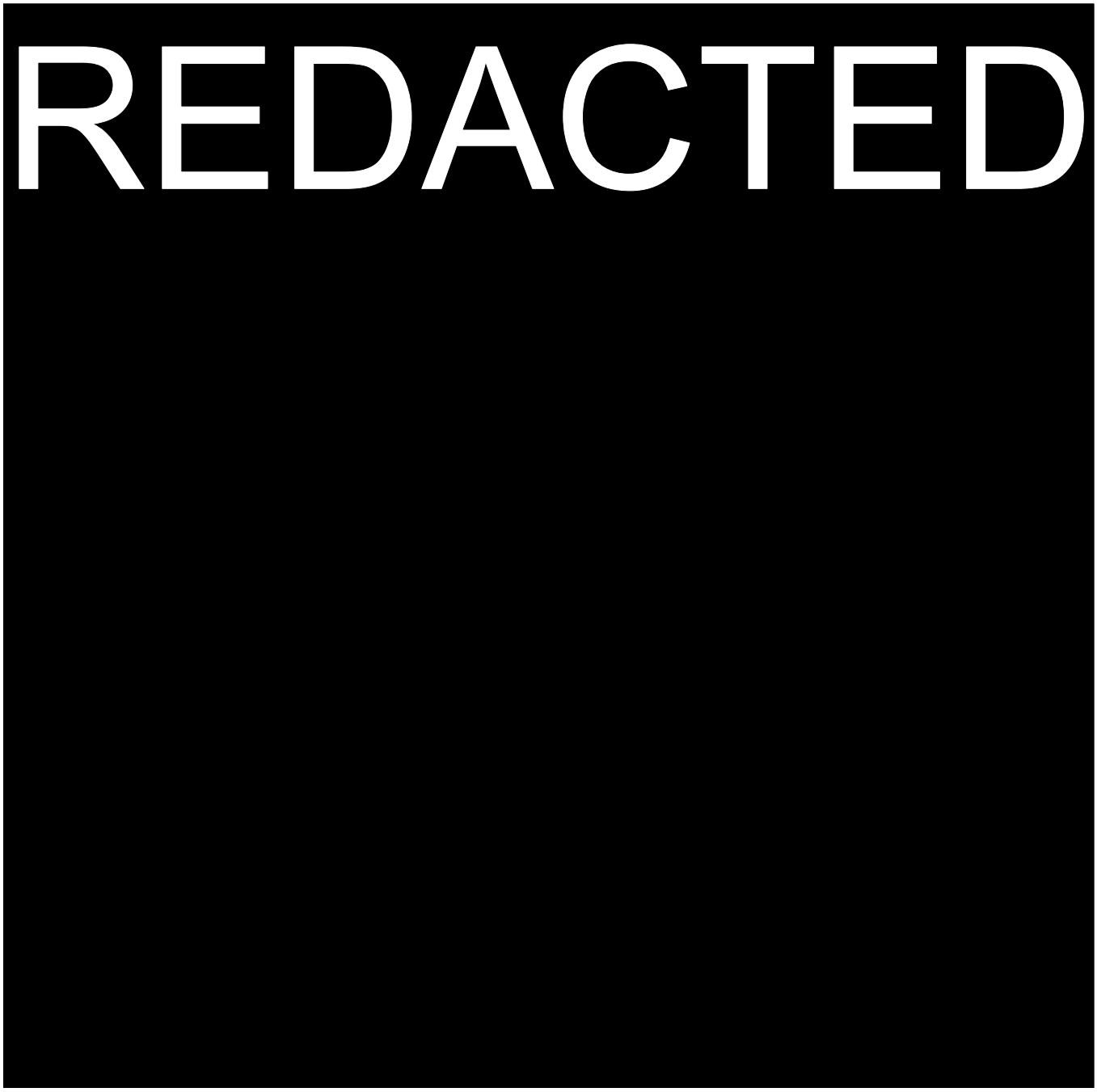
Accordingly, evidence of any acts of making, using and/or selling by Defendants to any prohibited commercial end-user or for any prohibited non-"research" purpose warrants denial of their motion. Further, any dispute by Defendants as to the contractual scope of those rights or restrictions and/or their application to the factual evidence of their accused activities presented by Enzo, at best, raises genuine disputes of material fact that cannot be resolved on summary judgment. *Record Club of Am., Inc. v. United Artists Records, Inc.*, 890 F.2d 1264, 1270-71 (2d Cir. 1989) ("Summary judgment as to the meaning of a contract term may not be granted when the term's meaning is not clear or is reasonably susceptible to more than one interpretation. Where contract language is ambiguous, the differing interpretations of the contract present a triable issue of fact.") (internal quotation omitted); *see also Consarc Corp. v. Marine Midland Bank, N.A.*, 996 F.2d 568, 573 (2d Cir. 1993) ("Where reasonable minds could be said to differ because the language the parties used in their written contract is susceptible to more than one meaning…[the question of the parties' intent] should be submitted to the trier of fact.").

B. Roche and PerkinElmer Sold Products for Commercial Purposes

1. Defendants Fully Understood that the Agreements Were Restricted to Non-Commercial Purposes

REDACTED

a determination of whether a contract was sufficient for a finding of personal jurisdiction. *Genetic Implant Sys., Inc. v. Core-Vent Corp.*, 123 F.3d 1455, 1458 (Fed. Cir. 1997).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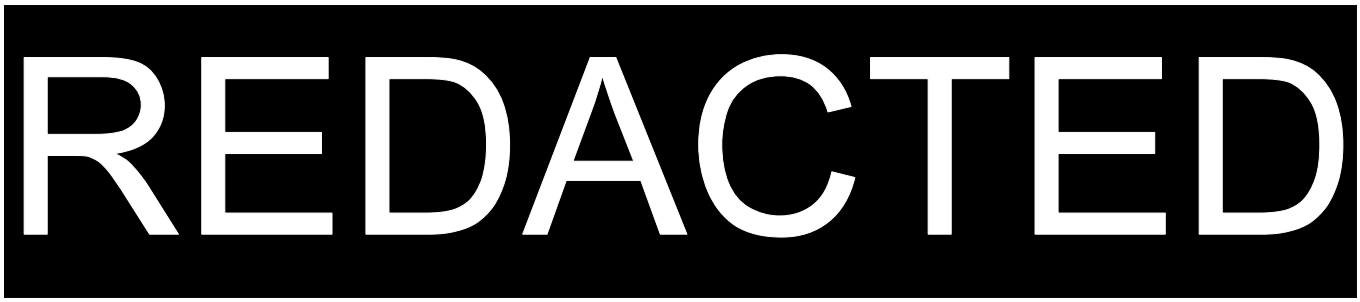
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2. The Record Evidence Confirms that Defendants Infringed by Exceeding the Contractual Scope of Authority

With full knowledge of the restrictions of the limited authority granted to them, PerkinElmer and Roche sold PRODUCTS for commercial purposes, including for the development of commercial products. REDACTED

REDACTED

REDACTED The record is also clear that Orchid contracted with NEN/PerkinElmer to provide PRODUCTS as reagents for its SNPstream systems which, in turn, were sold to, *inter alia*, large commercial entities such as SmithKline Beecham and Monsanto. (Ex. 59 at 15; Ex. 60 at 13 and 17; Exs. 61-63).

Likewise, Roche also used PRODUCTS for commercial purposes that exceeded its authority under its Agreement. REDACTED

REDACTED

REDACTED

Accordingly, in view of the above evidence of Defendants' "unauthorized" infringing activities, Enzo respectfully submits that summary judgment should be denied, particularly after drawing all reasonable inferences in favor of Enzo concerning the nature and purpose of the entities to which the accused products were provided and the uses that were made of them.

C. Roche and PerkinElmer Manufactured Products Without Authorization

REDACTED

[41] REDACTED

REDACTED

[42] Roche has not produced documents showing sales by product and customer for any time period. The documents attached to the Declaration of Horst Togonal in support of Roche's defense do not provide any customer or use-specific information and therefore have no bearing on whether those sales were authorized. Enzo sought documents and deposition testimony from PerkinElmer and Roche as early as December 2002, and followed up shortly after the instant motion was filed requesting supplementation of Roche's and PerkinElmer's document productions, and issuing an interrogatory and a deposition notice specifically tailored to the authorization defense. To date, Defendants have refused Enzo's discovery requests. While Enzo believes that the record evidence warrants outright denial of summary judgment, to the extent the Court is inclined to grant summary judgment as to any part of the authorization defense, Enzo

REDACTED

Both PerkinElmer and Roche admit to manufacturing the products subject to its "authorization" defense. (Renewed Motion at 35-36, "[PerkinElmer] always made all of the products that it sold under the distribution agreement (and Roche made most of them)"; and 39, "It is uncontroverted that all of the accused products were manufactured by and originated with Defendants."). REDACTED

REDACTED

REDACTED Defendants cannot possibly point to any other authority to exceed the explicit terms of their agreements. *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 (Fed. Cir.

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requests additional discovery under Rule 56(d) to determine whether Roche provided products to any commercial end-user for use, exploitation or product development. *See* MacLean 56(d) Decl.

[43] PerkinElmer's conflicting reading of Section 5, at best, only creates a genuine dispute of fact as to the meaning of the last sentence, precluding summary judgment. *Record Club of America*, 890 F.2d at 1270-71; *Consarc*, 996 F.2d at 573.

1984) ("[M]ere sale does not import a license except where the circumstances plainly indicate that the grant of a license should be inferred.") (internal quotations omitted).[44] Summary judgment as to these products should therefore be denied.

CONCLUSION

For all the foregoing reasons, Defendants' renewed joint motion for summary judgment should be denied in all respects.

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[44] A license cannot be implied by virtue of Defendants' "payment" to Enzo for unauthorized activities. To the extent PerkinElmer asserts this based on the inadmissible declaration of Paul LeBlanc, Enzo moves to strike it as not based upon personal knowledge as required by Rule 56(e). *In re Singer Co.*, CA No. 01-6839, 2002 U.S. Dist. LEXIS 8609, at *28-29 (S.D.N.Y. May 14, 2002) (declaration that sets forth the actions of a corporation and not the actions of the other employees from whom he received information for the declaration is not admissible evidence if not based on the personal knowledge of the declarant); *see also* Enzo's Statement of Material Facts Showing Genuine Issues to be Tried, No. 58 (setting forth the full basis for Enzo's objection). Further, as previously briefed regarding Enzo's contract claims, the payments made by each Defendant were inadequate. (*See* Ex. 73 at 6-7, 12-13; Ex. 74 at 9-10).